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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/065,280	09/30/2002	Jeffrey C. Leung	013341.000019	5694
24239 7590 12/28/2007 MOORE & VAN ALLEN PLLC P.O. BOX 13706 Research Triangle Park, NC 27709			EXAMINER DOWE, KATHERINE MARIE	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 12/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/065,280	Applicant(s) LEUNG ET AL.	
	Examiner Katherine M. Dowe	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.
2. Claims 1-98 are currently pending.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-3, 10-12, 14, 15, 25-31, 33-35, 37, 38, 63, 65-68, 95, 97, and 98 are rejected under 35 U.S.C. 102(b) as being anticipated by McKenzie (GB 1,091,282). Regarding claims 1 and 10, McKenzie discloses a barbed suture (Fig 6) wherein the barbs have an overlapping, or staggered, disposition (Fig 11). In the overlapping disposition, part of the underside of one barb is derived from part of the topside of an adjacent barb since the barbs are formed, or derived, from the same monofilament suture thread (pg 3, ln 128 – pg 4, ln 9).

Regarding claims 2, 26, and 67, the barbs may face in only one direction (Fig 6; pg 3, ln 48-51).

Regarding claims 3, 27, and 68, the suture may have a first barbed portion (35) that faces toward a first end (38) and a second barbed portion (36) that faces toward a second end (39) (Fig 9; pg 3, ln 103-109).

Regarding claims 11, 28, 29, and 30, the barb cut length of an overlapped barb is greater than the barb cut distance between adjacent barbs as shown in Fig 11.

Regarding claims 12, 14, 15, 31, 33-35, 37, 38, 63, 65, 66, 95, 97, and 98, the suture may be made from a non-absorbable material including nylon (a polyamide) or metal (pg 2, ln 64-65; pg 4, ln 40-46).

Regarding claim 25, the suture has at least two sets of barbs that are longitudinally offset with respect to each other as shown in marked up Figure 11 below, such that a plane cutting transversely through the suture and intersecting the base of a barb of the first set will not intersect the base of a barb of the second set.



Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4-9, 16, 17, 19-24, 39, 41-45, 47-51, 53-57, 59-62, 69-71, 73-77, 79-83, 85-89, and 91-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKenzie (GB 1,091,282). Regarding claims 4, 5, 16, 21, 23, and 24, McKenzie disclose the invention substantially as claimed including a barbed suture (Fig 6) wherein the barbs have an overlapping, or staggered, disposition (Fig 11). In the overlapping disposition, part of the underside of one barb is derived from part of the topside of an adjacent barb since the barbs are formed, or derived, from the same monofilament suture thread (pg 3, ln 128 – pg 4, ln 9). Furthermore, the overlapping disposition of the barbs may also be considered to be random because the cut angle, depth, length, and distance may not be exactly the same for each barb, but rather may differ by at least a minimal amount from barb to barb. However, McKenzie does not disclose the specific dimensions of the barb cut angle, the ratio of the barb cut depth to the suture diameter, the ratio of the barb cut length to the suture diameter, or the ratio of the barb cut distance to the suture diameter. Applicant has not disclosed that having the suture with a specific barb cut angle of 140-175 degrees, a specific ratio of barb cut depth to suture diameter of 0.05-0.6, a specific ratio of barb cut length to suture diameter of 0.2-2, or a ratio of barb cut distance to suture diameter of 0.1-6 solves any stated problem or is for any particular purpose. Moreover it appears that the barbed suture of McKenzie, or applicant's invention, would perform equally well with the suture having any appropriate dimension. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified McKenzie such that the suture had a barb cut angle of 140-175 degrees, a ratio of barb cut depth to suture

diameter of 0.05-0.6, a ratio of barb cut length to suture diameter of 0.2-2, and a ratio of barb cut distance to suture diameter of 0.1-6 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over McKenzie. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the suture of McKenzie to incorporate the above parameters since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges or the an optimum value involves only routine skill in the art (see *In re Aller*, 105 USPQ 233, *In re Boesch*, 617 F.2d 272, 205 USPQ 215, and MPEP 2144.05).

Regarding claims 6-9 and 22, the barbs may be interpreted to have a twist cut multiple spiral disposition, since they are formed by twisting a monofilament (33) to produce a cruciform shape (Fig 12), cutting the ribs (43) to produce the series of barbs (44), and twisting the suture in its longitudinal axis (pg 3, ln 128 – pg 4, ln 9). However, McKenzie does not disclose the specific number of times the suture is twisted per inch or the specific dimensions of the spirality angle. Applicant has not disclosed that having the suture twisted specifically 2 to 17 times per inch or having a spirality angle of 12-18 degrees solves any stated problem or is for any particular purpose. Moreover it appears that the barbed suture of McKenzie, or applicant's invention, would perform equally well with the suture twisted any reasonable number of times or at any reasonable spirality angle. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified McKenzie such that the suture was twisted 2 to 17 times per inch at a spirality angle of 12-18

degrees because such a modification would have been considered a mere design consideration which fails to patentably distinguish over McKenzie. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the suture of McKenzie to incorporate the above parameters since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges or the an optimum value involves only routine skill in the art (see *In re Aller*, 105 USPQ 233, *In re Boesch*, 617 F.2d 272, 205 USPQ 215, and MPEP 2144.05).

Regarding claims 17, 19, 20, 39, 41, 42, 45, 47, 48, 51, 53, 54, 57, 59, 60, 71, 73, 74, 77, 79, 80, 83, 85, 86, 89, 91, and 92, the suture may be made from a non-absorbable material including nylon (a polyamide) or metal (pg 2, ln 64-65; pg 4, ln 40-46).

Regarding claims 43, 49, 55, 61, 67, 69, 75, 81, 87, and 93, the barbs may face in only one direction (Fig 6; pg 3, ln 48-51).

Regarding claims 44, 50, 56, 62, 68, 70, 76, 82, 88, and 94, the suture may have a first barbed portion (35) that faces toward a first end (38) and a second barbed portion (36) that faces toward a second end (39) (Fig 9; pg 3, ln 103-109).

7. Claims 13, 18, 32, 36, 40, 46, 52, 58, 64, 72, 78, 84, 90, and 96, are rejected under 35 U.S.C. 103(a) as being unpatentable over McKenzie (GB 1,091,282), as applied to claims 1-7, 10, 16, and 21-25 above, in view of Branch (US 5,520,691). McKenzie discloses the invention substantially as claimed as shown above. However,

McKenzie does not disclose the suture is bioabsorbable. Branch discloses a similar barbed suture that may be formed from a nonabsorbable material if the connection is desired to be permanent; alternatively, the suture may be formed from a bioabsorbable material including polydioxanone if the connection is desired to be temporary (col 6, ln 28-33). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the barbed suture of McKenzie et al. such that it was formed from polydioxanone instead of nylon such that the suture may be bioabsorbable. Thus, the suture may be absorbed by the body at the end of its useful life and a second surgery would not be necessary to remove the sutures at a later time.

Response to Arguments

8. Applicant's arguments with respect to claims 1-3 regarding the added limitations of the multiple spiral disposition have been considered but are moot in view of the new ground(s) of rejection. The Examiner notes the claims in which limitations were added include the language "the barbs having a disposition on the body selected from the group consisting of..." and thus the rejection of claims 1-3 is based on the barbs having an overlapping disposition.

9. Applicant's arguments filed 10/31/2007 regarding claims 4-9 and 21-23 have been fully considered but they are not persuasive. Applicant argues the specific parameters related to barb disposition and barb configuration including radial barb spacing, cut distance, cut angle, cut depth, cut length, and spirality angle define a barbed suture with novel, non-obvious features, which provide significant, non-obvious

advantages over the prior art. Applicant contends that since McKenzie fails to disclose any of the recited features, it may be concluded that McKenzie fails to recognize and thus realize the advantages which the Applicant has achieved with its invention. The Examiner respectfully traverses the Applicant's remarks. Applicant has not provided evidence that the particular parameters for barb spacing, cut distance, cut angle, cut depth, cut length, and spirality angle are critical and would not have been obvious to one having ordinary skill in the art. Such rebuttal evidence showing the criticality of the claimed parameter ranges may include unexpected results, commercial success, and long felt but unsolved needs. The Examiner additionally notes it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges or the an optimum value involves only routine skill in the art (see *In re Aller*, 105 USPQ 233 and *In re Boesch*, 617 F.2d 272, 205 USPQ 215).

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine M. Dowe whose telephone number is (571) 272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
December 18, 2007



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER